MISSOURI BOARD OF PHARMACY

NEWSLETTER

DECEMBER 2016

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NEW FEDERAL LAW AND SCHEDULE II PARTIAL FILLS

On July 22, 2016, President Obama signed the Comprehensive Addiction and Recovery Act (CARA) into law which includes multiple provisions to address the nationwide opioid epidemic. As part of CARA, the federal Controlled Substances Act was amended to allow a pharmacist to partially fill any Schedule II controlled substance and then dispense the remainder within thirty (30) days.

Missouri BNDD regulation is currently stricter allowing partial fills only for long term care or terminally-ill dispensing, or when a pharmacy does not have the full quantity in stock to fill the prescription. 19 CSR 30-1.064. According to BNDD, the new federal law does not preempt Missouri's rule. BNDD will be meeting with the DEA and the Department to discuss changing Missouri's requirements. Until the rule is changed, Missouri pharmacies must follow BNDD's regulation.

CHECK AGAIN

MoHealthNet has reportedly reviewed several recent cases where pharmacies entered and billed MoHealthNet under the wrong prescriber. In some instances, pharmacy staff selected the wrong prescriber from the computer's drop-down menu which made it appear as if a prescriber may have been overly or improperly prescribing.

Missouri law requires that a pharmacist verify that prescription information is correct before dispensing. This duty includes verifying that the correct prescriber is listed. Staff should be trained not to guess and should contact the prescriber if the name is unclear. Licensees should also be careful with sound-alike names that could be easily confused in a drop-down menu (e.g., Dr. John Smith vs. Dr. Jon Smith).

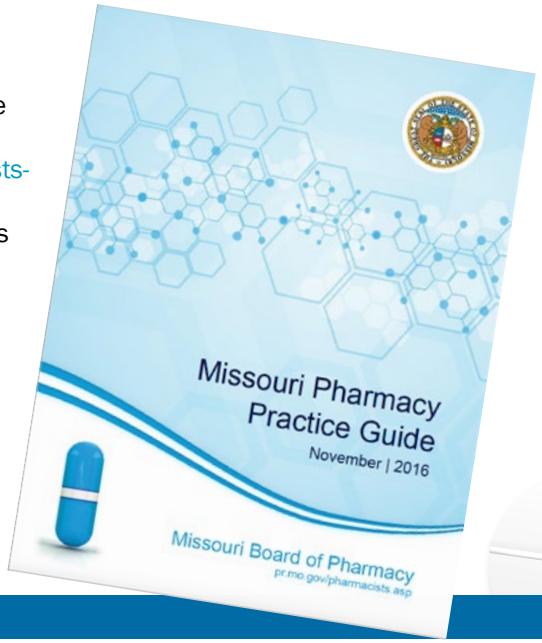
Prescription records must be accurate; Compliance violations may trigger a regulatory investigation.

THE 2017 PHARMACY PRACTICE GUIDE IS NOW AVAILABLE

The 2017 Missouri Pharmacy Practice Guide is now available online. The revised Practice Guide has been updated to include changes in Missouri law and additional inspector tips.

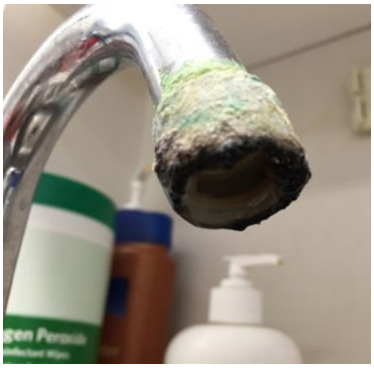
The Board has also updated the Pharmacy Self-Assessment Form which includes an interactive checklist of the most frequently reviewed compliance requirements. Two (2) hours of Board approved pharmacist continuing education (CE) credit is available for Missouri licensed pharmacists serving as a pharmacy manager, owner, supervisor, corporate officer or pharmacist-in-charge who complete the Self-Assessment.

The 2017 Pharmacy Practice Guide and Pharmacy Self-Assessment Form are available at http://pr.mo.gov/pharmacists-faq-compliance.asp. Compliance violations are preventable! Use the Pharmacy Practice Guide and the Pharmacy Self-Assessment Form to assess your pharmacy's compliance today.



INSPECTION TIP

Board inspectors observed the following faucet during a pharmacy inspection:



Pharmacy equipment and supplies must be clean and sanitary. Licensees should regularly check sinks, faucets and reconstitubes for dirt, mold and residue.

COMPLIANCE CORNER

(The following compliance cases were recently reviewed by the Board. This information is provided for educational purposes only. Each case is reviewed on its own merits.)

- A pharmacist substituted ergocalciferol for cholecalciferol without a valid prescription. The dispensing pharmacist indicated he thought the doctor had given "blanket authorization" to dispense ergocalciferol instead of Cholecalciferol. *Compliance Tip: A valid prescription is required to dispense any drug. "Blanket authorizations" are not valid for dispensing. Generic substitution was not allowed in this case since the products are different drugs. The pharmacist should have contacted the prescriber for a valid verbal or written prescription.*
- A technician diverted controlled substances from a pharmacy and hid the diversion by making inventory adjustments in the pharmacy's computer. Everyone employed by the pharmacy had access to the inventory system and could adjust the drug inventory without a reason. Adjustments were not regularly reviewed or verified. *Compliance Tip: This is a common diversion tactic! Pharmacies should have policies and procedures for monitoring and verifying inventory adjustments. The Board also recommends limiting the staff allowed to make adjustments. PICs should regularly review inventory adjustments to look for trends or irregularities (e.g., Are excessive adjustments being made by a single staff member? Are adjustments only being made for a specific drug?).*
- A patient was dispensed meclizine instead of meloxicam. Both the technician and pharmacist failed to catch the error and commented that the drugs sound alike. *Compliance Tip: Licensees should be particularly careful with drugs that sound alike. The Institute of Safe Medication Practices has an online list of commonly confused drug names that can be printed or downloaded for free at https://www.ismp.org/tools/confuseddrugnames.pdf. Review the list with pharmacy staff. Patient safety is everyone's responsibility.*
- A Missouri mail order pharmacy received a controlled substance prescription from a new patient located in Texas. The pharmacy contacted the patient to ask for a copy of the patient's ID and to verify the patient's mailing address. The patient provided a P.O. Box as her only mailing address and failed to provide all of the requested patient information. The pharmacy had no prior relationship with the patient and refused to fill the prescription. *Compliance Tip: Pharmacists have a corresponding responsibility to make sure prescriptions are dispensed for a legitimate medical purpose. When in doubt, ask! Pharmacists have the right to refuse to fill a suspicious prescription. Remember, it's your license.*
- A previously employed technician was suspected of diverting controlled substances from the pharmacy after she was terminated. The pharmacy's access codes were not changed after the employee's termination which may have allowed the former employee to access the pharmacy after hours without being detected. *Compliance Tip: Former employees can be a significant diversion risk! The Board recommends changing employee access codes whenever an employee leaves and changing the locks if keys are involved.*
- A technician diverted controlled substances from the pharmacy by placing multiple tablets in her smock pocket before going home. The pharmacy checked employee bags at the end of the day but did not check smock pockets. *Compliance Tip: Unfortunately, thieves can be creative. Look for pockets or bags where drugs can be hidden.*
- A pharmacy recently reported a controlled substance loss to BNDD. During the investigation, the PIC told the inspector the inventory count was wrong for over six (6) months. The PIC did not investigate the discrepancy or do a reconciliation because she thought corporate would handle it. *Compliance Tip: PICs are personally responsible for compliance and that includes making sure adequate security is in place to prevent controlled substance losses. The Board strongly recommends that pharmacies regularly reconcile their inventory. A how-to guide for reconciling drug inventory is available on the Board's website at http://pr.mo.gov/pharmacists-faq-compliance.asp .*

2019 RULE REVIEW

Section 536.175, RSMo, requires state agencies to periodically review their rules for fairness, consistency and appropriateness and to file a report with the Missouri Joint Commission on Administrative Rules. As part of the statutorily required review, the Board is asking for public comment on the following rules on or before **January 10, 2017:**

- 20 CSR 2220-2.005 (Definitions)
- 20 CSR 2220-2.010 (Pharmacy Standards of Operation)
- 20 CSR 2220-2.015 (Termination of Business as a Pharmacy)
- 20 CSR 2220-2.016 (Pharmacy Operating Procedures During Declared Disasters)
- 20 CSR 2220-2.020 (Pharmacy Permits)
- 20 CSR 2220-2.025 (Non-Resident Pharmacies)
- 20 CSR 2220-2.090 (Pharmacist-In-Charge)
- 20 CSR 2220-2.700 (Pharmacy Technician Registration)
- 20 CSR 2220-2.900 (Automated Dispensing and Storage Systems)
- 20 CSR 2220-2.080 (Electronic Prescription Records)
- 20 CSR 2220-2.083 (Electronic Record-Keeping Systems)

Comments may be submitted online, e-mailed to MissouriBOP@pr.mo.gov or mailed to the Board office. The full rule review calendar is available on the Board's website at http://pr.mo.gov/boards/pharmacy/RuleReviewCalendar.pdf.

GOLD CERTIFICATES

The following pharmacists have maintained a Missouri pharmacist license for 50 years. Congratulations to our newest "gold-certificate" pharmacists:

Gary L Burcham
Robert G Flynn
Judith H Evans
James G Evans

DISCIPLINARY ACTIONS

PHARMACISTS:

Jason M. Barczewski, #2007034304, St. Louis, MO. Public censure. Received prescriptions not lawfully authorized by a physician. Section 338.055.2(5), (6), (13), and (15), RSMo.

Allison Gates (McIlvaine), #2010026492, Foley, AL. Five (5) years probation. Admitted to being under the influence of alcohol while practicing. Section 338.055.2(2), (5), and, (13), RSMo.

Nancy P. Onyon, #2009029566, Catoosa, OK. Three (3) years probation. Misappropriation of controlled substances from employer for personal use. Section 338.055.2 (5), (6), (13), (15), and (17) RSMo.

Andrew G. Palans, #042773, Lake Saint Louis, MO. Probation for three (3) years. As Pharmacist-in-Charge, dispensed controlled substances without a valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Section 338.055.2 (5) (6), and (13), RSMo.

Uldis V. Pironis, #040806, Jefferson City, MO. Probation for one (1) year. As pharmacist-in-charge, instructed technician to compound and dispense without a pharmacist present and without required supervision. Section 338.055.2(6), (10), and (15), RSMo.

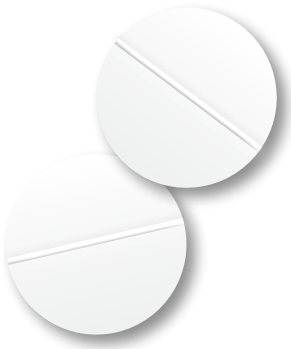
James H. Williams, #029907, Blue Springs, MO. Probation for five (5) years. Disciplinary action in Kansas relating to diversion of controlled substances for personal use. Section 338.055.2 (1), (5), (13), (15) and (17), RSMo.

PHARMACIES:

Jefferson City Apothecary, #2003010139, Jefferson City, MO. Probation for one (1) year. Pharmacist-in-charge instructed technician to compound and dispense without a pharmacist present and without supervision. Section 338.055.2(6), (10), and (15), RSMo.

Harbor Compounding & Home Health Pharmacy, permit #2013042651, Costa Mesa, CA. Probation until 07/15/20. Entered into a Stipulated Settlement and Disciplinary Order with the California Board of Pharmacy for sterile and non-sterile compounding violations, failure to maintain records, failure to properly test sterile compounds and failure to disclose required ownership information. Section 338.055.2 (5), (8), and (13), RSMo.

Wharf Pharmacy, permit #003121, O'Fallon, MO. Probation for three (3) years. Dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Inaccurate records, failure to keep records in a uniform fashion for at least 5 years. Section 338.055.2 (5) (6), and (13), RSMo.



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 4TH QUARTER 2016

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

NATIONAL VACCINE SAFETY SURVEILLANCE PROGRAM AVAILABLE FOR REPORTING ADVERSE EVENTS

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at https://vaers.hhs.gov/professionals/index.

IMPROPER AND UNSAFE VACCINE STORAGE

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.2

References

1. ISMP. Recommendations for practitioners to prevent

vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). ISMP Medication Safety Alert! 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

COALITION REPORTS IMPACT OF EDUCATIONAL EFFORTS ON SAFE ACETAMINOPHEN USE

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

1. Read and follow the label.
2. Know which medicines contain acetaminophen.
3. Take only one medicine at a time that contains acetaminophen.
4. Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, www.knowyourdose.org.

FDA OFFERS WEBINARS ON ONLINE DRUG INFORMATION RESOURCES FOR STUDENTS AND CLINICIANS

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

FRESENIUS KABI RECALLS SENSORCAINE-MPF (BUPIVACAINE HCL) INJECTION, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at www.fda.gov/MedWatch. Additional details are available on FDA's website at www.fda.gov/Safety/Recalls/ucm497812.htm.

ORAL LIQUID DOCUSATE SODIUM BY PHARMATECH RECALLED DUE TO CONTAMINATION

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with Burkholderia cepacia, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of B. cepacia infections in patients, and some of these reports

identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. More information may be found in the safety alert on FDA's website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm.

NABP SEEKS PHARMACISTS FROM DISTRICTS 1, 5, AND 7 TO SERVE AS VOLUNTEER ITEM WRITERS

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.